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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003905192 for a patent by DAVID PETER WHARTON as filed on 24 September 2003.



WITNESS my hand this
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JULIE BILLINGSLEY
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David Peter Wharton

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PROVISIONAL SPECIFICATION

for the invention entitled:

"Medication Holder"

The invention is described in the following statement:

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TITLE

"MEDICATION HOLDER"

FIELD OF THE INVENTION

THIS INVENTION relates to a device for securely storing a container
5 holding medication for use by a person. In particular, the invention relates to a device for
holding medication provided for inhalation or ingestion. The device is particularly suitable
for use by a person when mobile and may be well suited for use during sporting activities,
but is not so limited. Operation of the device facilitates access to the medication for
administration.

10

BACKGROUND OF THE INVENTION

The evolution of devices for self-medication has been of great advantage to
sufferers of various diseases and pathologies.

One prime example is that of asthma. In earlier times, sufferers of asthma
were typically sentenced to a lifetime of disability, often based on arranging their life
15 around low levels of physical activity or restricted ranges of travel, so that they could be
close to support mechanisms provided in their own environment. Severe bouts of asthma
often required the attention of professionals, such as doctors, and the use of drugs
administered by those professionals. These drugs, which included aminophylline and
adrenaline, had reasonable levels of efficiency but also brought with them some significant
20 risks of use. Further, the use of these drugs was a late stage step in the process and did not
provide any ongoing advantage to a patient in the way of control and stabilisation of the
disease condition.

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The development of corticosteroids was of great assistance in some diseases and, in particular, asthma. However, the side effects of prolonged oral or parenteral administration of corticosteroids in people are notorious and necessitates restrictions on the adoption of this approach in other than the most severe cases.

5 A dramatic improvement in the quality of life of sufferers of asthma arose with the development of pressurised medicated containers designed for the self-administration of salbutamol, a bronchodilator, which is very effective in counteracting the bronchospasm of an asthma attack. Salbutamol is usually provided in a pressurised container with a depression-activated valve at its top. The valve is configured to nest in a
10 seat provided on an outer plastic collar, cap or mouthpiece. This collar allows the depression of the canister relative to a valve stem, thereby releasing a controlled dose of therapeutic agent into a discharge throat of the collar. A patient uses the device by exhaling to a greater or lesser extent and then inhaling while depressing the canister to discharge a dose of the agent.

15 As well as providing the ability to treat an attack of respiratory embarrassment, the salbutamol inhalers have provided the ability to self-administer a regime of treatment to thereby minimise clinical signs and allay or prevent further development of the respiratory attack.

 Salbutamol is an excellent example of a suitable therapeutic agent for self-
20 delivery but is by no means alone. Many other forms of therapy have been provided for asthma (for example, Becotide, Flexitide, Asmol). Additionally, many other diseases lend themselves to self-medication through the provision of a metered dose, either into the

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respiratory tract or for ingestion through the gastrointestinal tract or absorption through the mucous membranes of the oropharynx or the nose.

Provision of the medication may be in a form as described, being a compressed pressurised aerosol formulation. Alternatively, powder or other solid
5 formulations or even liquids or gases may be provided and dispensed at a set dose. Separate individual doses of medication may be provided in a capsule or similar form and adapted for release in devices often referred to as medihalers. These devices may have a rotatable vane which is activated by a patient breathing in, thereby distributing the medication into the airstream. In some arrangements a fine powder may be simply
10 breathed into the lungs.

While these developments have been of tremendous utility to sufferers of diseases that lend themselves to effective self-medication, there has been an ongoing problem of patients either forgetting their medication canisters or mistakenly believing they are stored somewhere, such as a handbag or sports bag, only to find the medication is
15 not available for use when required. This can, of course, have serious consequences in the event of a sudden severe onset of disease signs and symptoms. The problem of effectively and safely storing medication canisters is exaggerated in sporting activities where clothes are often designed for the specific requirements of the sport being undertaken, but with no provision of secure pockets or pouches. Even when pockets are provided, the presence of
20 a hard object carried in such a pocket may be uncomfortable, irritating or even performance-restricting in a competitor. The problems may be pronounced in activities, such as snorkelling, scuba diving, orienteering and mountaineering where a sufferer of a

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condition may find themselves a considerable distance from a support based with little else other than gear required for the activity.

Reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form of suggestion that this prior art forms part of the
5 common general knowledge in any country.

SUMMARY OF THE INVENTION

In one form, although it need not be the only or indeed the broadest form, the invention resides in a housing for a medication canister or arrangement, the housing comprising:

10 a first wall defining a cavity dimensioned to receive and enclose, at least in part, the medication canister or arrangement;

a second wall abutting the first wall and moveable relative thereto;

wherein:

the second wall may be positioned in a first closed position or, alternatively,
15 in a second open position, the second open position providing or facilitating access to a medication discharge outlet of the medication canister or arrangement.

The first wall may be an inner wall. The second wall may be an outer wall in a sleeved relationship to the inner wall. "Enclose, at least in part, the medication canister or arrangement" may comprise sealingly enclosing the canister or arrangement
20 through an encircling wall or a wall that elastically abuts against a wall of the canister or arrangement to resist ingress of moisture or other contaminant.

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The housing may be formed from any suitable material, but is preferably formed from a durable polymer such as PVC, PEEK or PET or an alloy such as aluminium.

5 The housing is preferably formed of components that may be moulded or extruded.

The medication canister may comprise a pressurised canister. The canister may be adapted to release a controlled dose of therapeutic agent. The canister may preferably contain multiple doses of the therapeutic agent. The medication arrangement may be understood to extend to a mechanism that is pressurised or activated by the through
10 flow of air inhaled by a user. This may include a rotatable impeller.

The first inner wall may define an enclosed bore dimensioned to receive the medication canister. The first inner wall may be a continuous wall. The bore may be open at one or both ends. A first end region of the first inner wall adjacent a first opening may be adapted to engage a flexible membrane. The flexible membrane may be formed as a
15 concertina-type membrane. The flexible membrane may be engageable with the first end region in a watertight or water-resistant manner. The flexible membrane may be adapted for transferring a depressing force from a user's hand to the medication canister to activate it when aligned for use. The flexible membrane may be formed as a thumb pad.

Alternatively, the first end region may be formed as a closure of the bore,
20 the closure operable to provide an air flow pathway through the bore. The closure may be twist operated and may be also adapted to advance a medication dose into position for inhaling.

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The medication arrangement may comprise a depot of medication and dispersal means for distributing the medication for ingestion or inhalation. The dispersal means may be a rotatable vane or impeller. The depot may comprise one or more capsules, each storing a dose of medication and arranged to rupture when in position for
5 dispersal.

A second end region of the inner wall may abut a second end aperture of the bore. The second end aperture may be formed as a lateral aperture.

Preferably, the bore contains a mouthpiece for receiving a valve end of the canister, the mouthpiece comprising a seat for receiving the canister and a medication
10 channel adapted to direct a dose of medication in a desired direction.

Preferably, the mouthpiece is pivotally mounted and rotatable between a first stowed position and a second deployed position, wherein the channel is positioned to deliver medication to a user. The mouthpiece may be pivoted between the stowed and deployed positions manually. Preferably, the mouthpiece is biased towards the deployed
15 position. The mouthpiece may be biased towards the deployed position by spring means. The mouthpiece may include an air intake vent.

The inner wall may define an end region of the housing.

The inner wall preferably is dimensioned to provide a recess or recesses to hold one or more additional medication canisters. The one or more additional medication
20 canisters may be stored substantially parallel to the medication canister.

The outer wall is preferably movable relative to the inner wall by sliding. The outer wall may be formed as a sleeve member for partially or completely encircling the middle wall for at least a portion of the inner wall's length. Preferably, the outer wall

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is slidable into a closed position abutting the end planar region and an open position in a direction away from the end planar region. The second wall may be removed during operation. Preferably the outer wall remains in a sleeved, abutting position with the first wall.

- 5 The housing may include sealing means for providing a water-resistant seal between the outer and inner walls when the outer wall is in a closed position. The sealing means may comprise one or more seals, preferably O rings, positioned in either the outer wall or the inner wall, but preferably in the outer wall.

- The housing preferably further comprises attachment means for attaching
10 the holder to an item such as a sports bag or, preferably, to a user. The attachment means may be an eye and strap arrangement for positioning the device around the neck of a user or around a portion of a sports bag or similar.

- Preferably, the attachment means is a band adapted for positioning around the limb of a user or around a strap of a bag or similar. The band is preferably a wristband.
15 The housing may be attached to the wristband in any suitable fashion. In its most basic form, the band may be required to be removed for use of the medication canister.

- Preferably, however, the housing is fixed to the band by a pivot fitting which permits the housing to be rotated between a first position, wherein it is substantially aligned with the longitudinal axis of a user's arm and a second position where it is
20 substantially transverse to the longitudinal axis and thereby accessible for easy use.

 The band may be fixed by any standard means, such as a buckle or Velcro strap. The band may be elasticised. The band may further incorporate other items such as

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a diving watch, stopwatch, alarm or other items sometimes required during outdoor and sporting activities.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front view of a preferred embodiment of a housing of the present invention incorporating a spare medication canister;

FIG. 2 is a sectional arrangement of FIG. 1;

FIG. 3 is a front view of the arrangement of FIG. 1 when deployed for use;

FIG. 4 is a perspective view of the arrangement of FIG. 3;

FIG. 5 is a front view of a second embodiment of a housing for a single medication canister;

FIG. 6 is a sectional view of the arrangement of FIG. 5 when inverted for use;

FIG. 7 is a sectional view of the arrangement of FIG. 6 when deployed for use;

FIG. 8 is a side sectional view of a further embodiment of a housing of the present invention;

FIG. 9 is a side view of the housing of FIG. 8;

FIG. 10 is a side section view of the arrangement of FIG. 8 when configured for use;

FIG. 11 is a perspective view of the configuration of FIG. 10;

FIG. 12 is a sectional view of yet another embodiment of a housing;

FIG. 13 is a front view of the housing of FIG. 12;

FIG. 14 is a side view of the housing of FIG. 13;

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FIG. 15 shows the housing of FIG. 13 when ready for use;

FIG. 16 is a preferred embodiment of the arrangement of FIG. 2 when mounted to a wristband;

FIG. 17 is an exploded view of the arrangement of FIG. 16.

5

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to FIG. 1, there is seen a housing which in this case is exemplified by a medication holder 10 comprising an inner wall 11 and outer wall 12.

The inner wall 11 is formed as a continuous wall and is substantially in the shape of a figure 8 arrangement in cross-section. An intermediate recess 13 defines the
10 border between a first active bore 15 and second storage bore 16.

A first end region 17 of the active bore 15 is capped with the flexible membrane 18, which may also extend across the end of the storage bore 16 to thereby seal both bores. The storage bore 16 may be capped by a separate cap 19 to provide independent operation of the two capping mechanisms. However, in general, it is
15 envisaged that the end capping arrangement would be continuous to allow easy removal and subsequent positioning of a fresh canister in the active bore 15 with subsequent recapping for use. It should be noted, however, that the device may be able to be used without the end cap at all. The wall of the first bore 15 may be attached to a flexible skirt-like structure (not shown) with an aperture for receiving and snugly adjoining the wall of
20 the medical canister. A resilient diaphragm may be positioned in the bore to sealingly engage the wall of a canister to thereby isolate the mouthpiece and render it waterproof.

In some embodiments, the canister may comprise an arrangement for delivering a solid therapeutic agent, such as in powdered form, or indeed a liquid

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therapeutic agent. In this case, it may be desired to have a through bore which is patent and allows the inspiration of air flowing through the bore and canister arrangement to activate a spinhaler or similar and disperse a therapeutic agent. The through bore may also be provided for use with a pressurised canister. The spinhaler may be provided with
5 powder carried in a separate capsule or similar arrangement. The capsule may be mounted in a seat in the bore and pierced to release powder for subsequent inhalation. In this case, the storage bore may in fact be adapted to store solid medication, preferably in the form of powder. The powder may be in individual doses formed in gelatin capsules or similar. Alternatively, the powder may be provided as a bulk quantity with a measuring spoon for
10 loading into the active bore. The term "medical arrangement" therefore can be viewed as extending to these arrangements which provide a means of medicating an airstream delivered to the mouth or nose.

In this embodiment, a neck strap 20 is shown mounted to a receiving eye 21. The neck strap allows the positioning of the housing 10 around the neck of a user.
15 In the subsequent discussion, it will be seen that a user may simply slide the outer wall 12 into an open position with the holder inverted for immediate and easy use.

The internal arrangement of the device of FIG. 1 can be seen in FIG. 2. A first pressurised metered dose inhaler 22 is positioned in the active bore 15.

The flexible membrane in the form of a cover cap 18 is seen to be an
20 integral unit which sits above an activation button 23. The canister 22 has a valve stem 24 positioned in a seat 25 in a cap or mouthpiece 26. The valve stem has a discharge channel 27 leading to a discharge aperture 28 in the mouthpiece or top cap 26. The mouthpiece 26 is pivotally mounted on stud 29 and tensioned by a spring 30. The spring 30 biases the

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mouthpiece into a deployed position. O ring seals 31 are provided to resist the ingress of moisture and water during use. The presence of the seals is preferred as it lends great utility and robustness to the holder, thereby making it suitable for use in wet environments, in forest and bush settings, in mud and around dust and other potentially dangerous
5 environmental features. The seals are located between the two walls and may be formed of any suitable polymer such as rubber or silicon-based material. Preferably, the seals provide a limited resistance to the sliding of the outer wall 12 over the inner wall 11.

A spare canister 32 is seen in position. The canister may contain the same agent as the pressurised dose canister 22. Alternatively, the canister may contain a
10 different therapeutic agent, thus allowing the holder to provide alternative forms of medication. It is also clear that the holder may be designed to carry two or more spare canisters, each being a duplicate or a source of an alternative therapeutic agent.

FIG. 3 shows a front view of the arrangement of FIG. 1 with the outer wall 12 slid into its open position, thereby clearing the bore containing the canister. The bore
15 also provides space 33 for location of the mouthpiece 26 when in rotated stored position.

The mouthpiece 26 is directed outwardly of the medication holder and positioned for easy access by a user. The mouthpiece may include an air intake vent or vents (not shown) to provide inhalation air when a user places his or her lips on the mouthpiece.

20 FIG. 4 provides a further perspective view of this arrangement.

FIG. 5 shows an embodiment in which a single canister is installed in the medication holder 40. An inner wall 41 is surrounded by an outer wall sleeve 42 for a

- 12 -

portion of its longitudinal length. This embodiment again has a neck strap 43. It also has a concertina-like flexible membrane cap 44 on a first end of the inner wall 41.

While it is generally preferred that the inner and outer walls are formed from the same material, it is possible to use different materials for each of the components.

5 The walls may be formed from lightweight durable polymers but could also be formed of metal. The outer wall 42 is shown with grip-enhancing pads 45 to facilitate use.

While emphasis has been placed on the use of therapeutic agents, it is also clear that the medication holder may store non-medical agents such as vitamin supplements, energy-boosting substances, electrolyte replacements and similar. One
10 example of such a material may be glucose for diabetes sufferers for use in the event of a hypoglycaemic episode arising. Simple application of glucose may be sufficient to raise the blood glucose levels and prevent the risk of hypoglycaemic signs including the life-threatening possibility of a hypoglycaemic coma. While such a person would clearly be suffering from a disease condition, the use of glucose in endurance athletes or for athletes
15 in extreme conditions may be of considerable advantage in maintaining their homeostasis and circulatory equilibrium in an otherwise fit and pathology-free person. The medication may be directed to gastrointestinal absorption as opposed to respiratory tract targeting.

FIG. 6 shows the arrangement of FIG. 5 inverted and in a stowed position. The canister 46 is apparent, as is the mouthpiece 47 and O ring seals 48.

20 In FIG. 7, the outer wall 42 has been slid in the upward direction of arrow 49, cleared the bore 50 and allowed the mouthpiece 51 to pivot in the direction of arrow 52. This time, pivoting is in a front-to-back direction around pivot pin 53 and under the effect of spring 54. The holder 40 therefore does not require lateral storage space in

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the bore and allows storage of the mouthpiece in an up and down bore under the end or top region 55.

An alternative embodiment is shown in FIG. 8 in which the housing is exemplified by a medication holder 65 having an outer wall 66 and inner wall 67. The latter inner wall 60 forming a bore 68. A wad of moisture absorbing material 69 is placed in the bore next to an end twist base 70. A dry powder reservoir 71 is provided which is formed by a concentration of medication material. A secondary reservoir 72 contains a single dose of the powder and is refilled from the reservoir 71. A mouth piece 73 is stowed by rotation around pivot point 74 with the outer wall 66 positioned to retain it in a retracted location as shown. O ring seals 75 provide a barrier to ingress of unwanted materials. A flow path 76 is formed to lead away from an inhalation area 77.

FIG. 9 shows a view of the device 65 with an arrow 78 indicating the direction in which the outer wall 66 will slide relative to the inner wall in operation. It is within the concept of the invention to reverse the inner and outer walls and have the inner wall slide inside the outer wall to release the mouthpiece.

FIG. 10 shows the mouth piece 70 rotated around the pivot point 74 and in working position relative to the flow path 76. The end twist base 70 may be rotated to move the dose in the secondary reservoir 72 into the inhalation area 77. Rotation of the twist base 70 opens and creates a patent air pathway from the twist base 70 through to the mouthpiece 73. A user may then inhale through the mouthpiece 73 pulling air through the device and entraining the powdered medication for subsequent inhalation. Further doses of the compound may be provided by additional twisting of the twist base, preferably in a reciprocating action.

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FIG. 11 shows the components as seen in a perspective. In this case, the twist base forms a closure but when activated provides a patent air path through the device. An end section 78 acts as a top cap for the medication holder.

A cross section of yet a further embodiment of a housing is shown in FIG. 12 in which a medication holder 80 is seen in side sectional view. The medication holder 80 has a mouthpiece 81 and drug delivery point 82.

A geared arrangement shown generally as 83 is configured to operate a blister pack roll 84 formed of a flexible backing material with blister packs containing predetermined doses of medication. Operation of the geared arrangement 83 may be through the action of sliding outer wall 85 over the inner wall 86 thereby causing rotation of the gears, advancement of the blister pack roll 84 and rupture of one blister pack at the drug delivery point 82 to present the medication for inhalation. The device may be provided with a neck strap attachment 87.

FIG. 13 shows the device in side view with finger grips 88 apparent.

FIG. 14 shows the slim line nature of the device which allows it to be formed as an easily carried and unobtrusive but fully closed package.

FIG. 15 shows the medical hold 80 with outer side wall 85 slid out of alignment with an O-ring seal 89 thereby exposing the mouth piece 81 allowing a user to access it and inhale the medication provided from the ruptured blister pack. Movement of the wall 85 both advances the blister pack roll as well as clearing an aperture to permit through flow of air once a user inhales while engaging the mouthpiece.

FIG. 16 shows a preferred embodiment in which a medication holder 60 is rotatably mounted to a wristband 61, in turn, mounted on the arm 62 of a user. The holder

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may be rotated in the direction of arrow 63 for deployment for use. When not in use, the longitudinal axis of the holder 60 is substantially parallel with that of the arm 62, thereby providing a neat and non-extruding profile when being carried by a user. When required, the holder 60 may be rotated through 90° and the outer wall 64 slid clear of the aperture
5 leading to rotation and presentation of the mouthpiece (not shown). In this orientation, a user may simply bring his or her forearm up to alignment with the user's mouth or nose. In this case, the outer wall 60 may have a slotted underside to allow movement relative to the pivotal mounting. Once used, the outer wall 60 may be then slid back into a closed position and the holder rotated back through 90° for its carriage position. The method of
10 attachment to the wristband may be any suitable arrangement such as friction plates or rotation plates with indentations for preferred positioning.

While a straightforward band 61 is shown in this view, it is clear that mounting arrangements may be fixed to other items commonly worn on the wrist such as watches, depth gauges, stopwatches, altimeters and heart rate monitors

15 The arrangement of FIG. 16 is shown in exploded view in FIG. 17 of the medication holder 60 coupled to a wrist mount attachment 90 which in turn fits into a seat 91 on a plate 92 which is continuous with wristband 61. Small lugs 93 act as stops to prevent rotation. Use of appropriate rotational force will overcome this resistance and cause the medication holder to rise up and rotate through 90° to the next lug. Additional
20 force may keep the device rotating but it is envisaged that a range of 90° will be adequate to discharge the function of the device.

The present invention provides a considerable number of advantages. A medication source may be easily and conveniently carried by a person in virtually any

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circumstance. A preferred circumstance is in the sporting or outdoor arena where the medication holder may be formed as a substantially waterproof item with robust and hardwearing characteristics that make it difficult to damage while providing easy and instant access to a hygienic and ready-to-use medication source. Many people with asthma
5 have a degree of embarrassment about the use of inhalers and similar and in publicly displaying their canisters. The present invention provides an effective way of carrying the canister in a fashionable and stylish way which may address at least some of this inhibition. The housing may be provided in a coloured arrangement with or without advertising indicia. They may be provided by sports promoters or pharmaceutical
10 companies as well as made available for private purchase. The medication holder may be used in sports in a wide range of terrains and, in fact, in any terrain or environment that is accessible by a participant. Carrying or wearing the medication canister or even locating it in association with a carried item or object will lead to minimal or no interference with performance by an athlete.

15 While the emphasis is on sports use, it is also clear that any potential user of a medication carried in a canister may find a reason for and advantage in using the present housing.

Throughout the specification, the aim has been to describe the preferred embodiments of the invention without limiting the invention to any one embodiment or
20 specific collection of features. Those of skill in the art will therefore appreciate that, in light of the instant disclosure, various modifications and changes can be made in the particular embodiments exemplified without departing from the scope of the present

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invention. All such modifications and changes are intended to be included within the scope of the above disclosure.

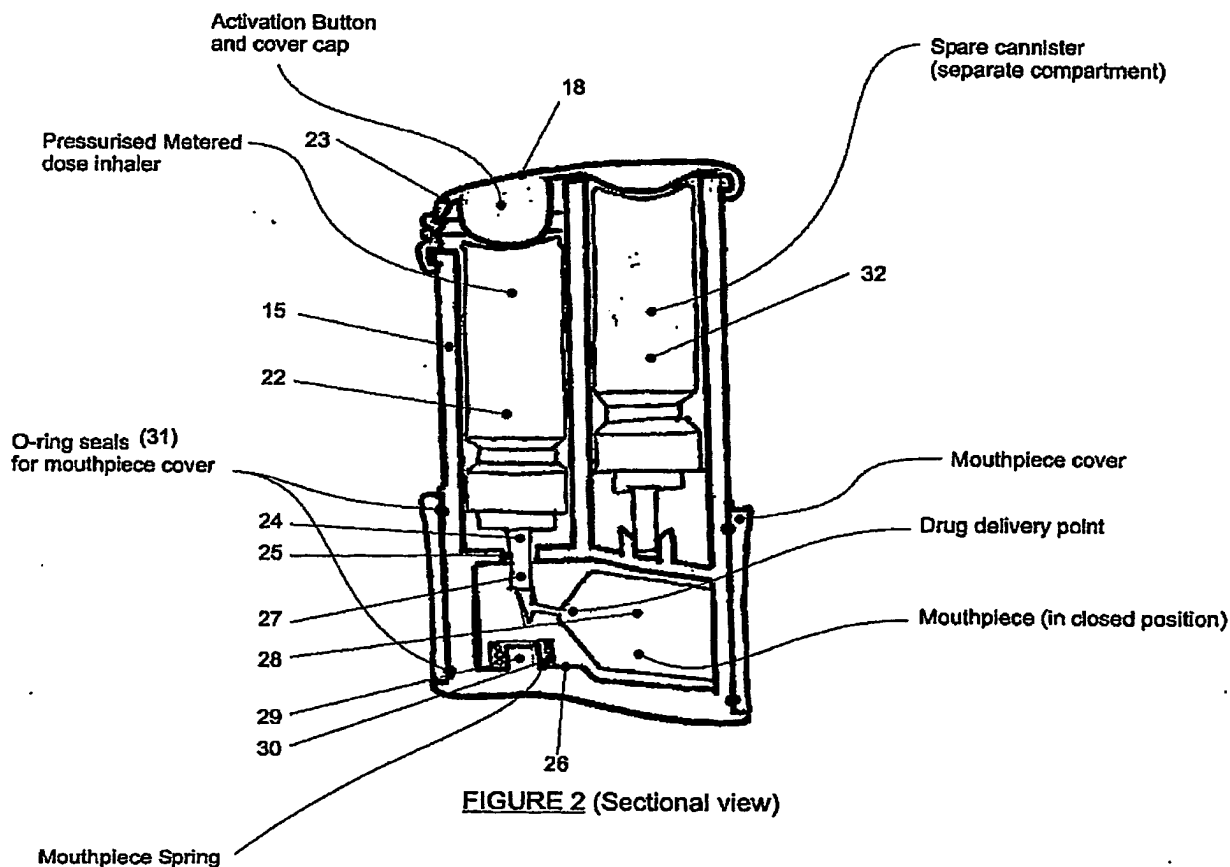
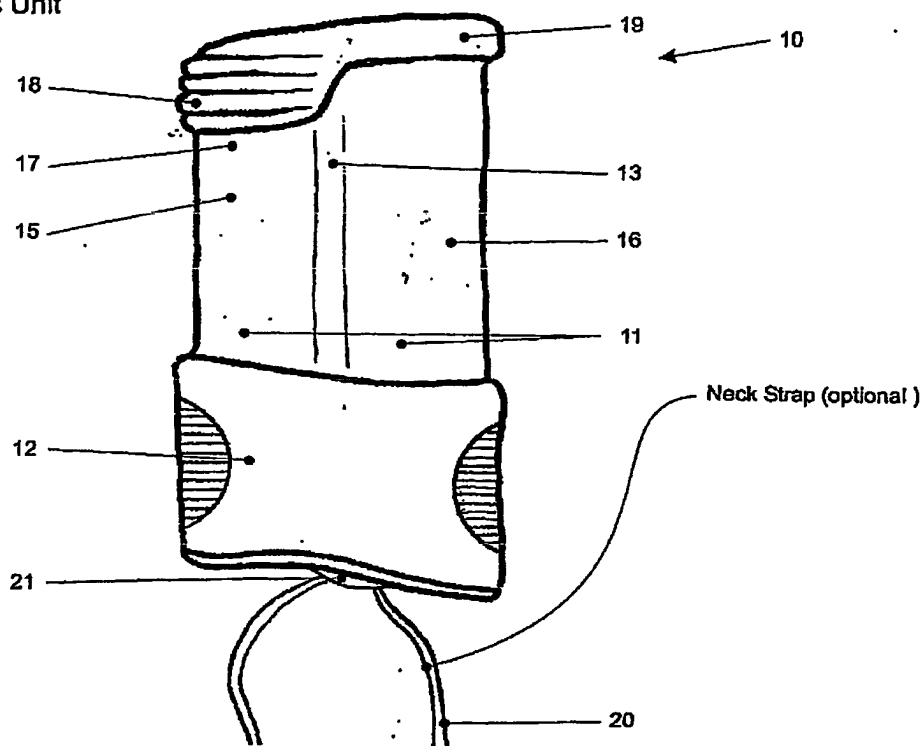
DATED this 24th day of September 2003.

DAVID WHARTON

By DAVIES COLLISON CAVE

Patent Attorneys for the Applicant

Medidive Active Sports Unit



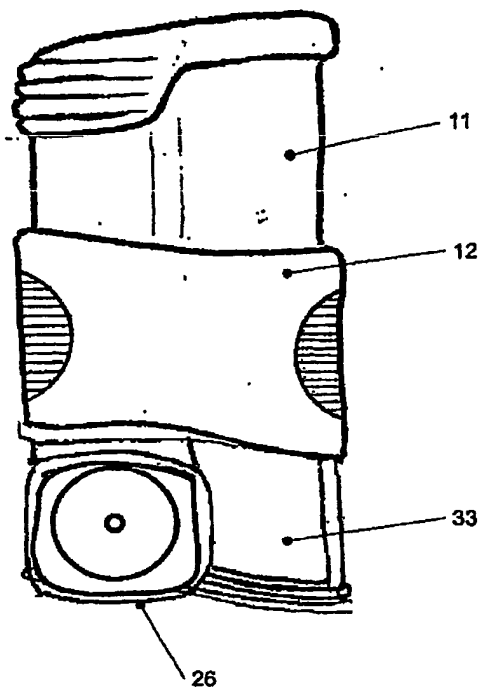


FIGURE 3.

Mouthpiece (in open position)

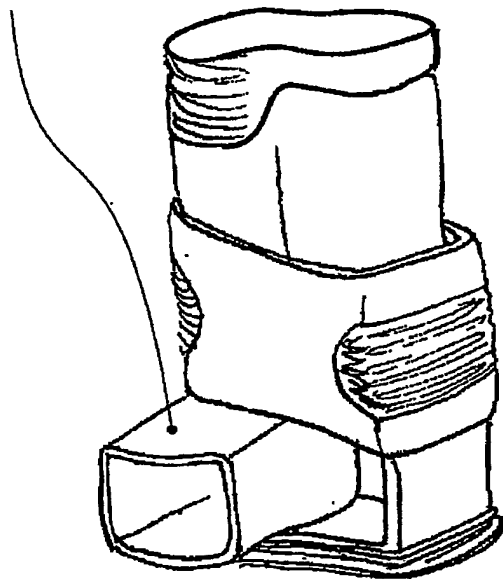


FIGURE 4.

Medidive Active Sports Unit (Single Cannister)

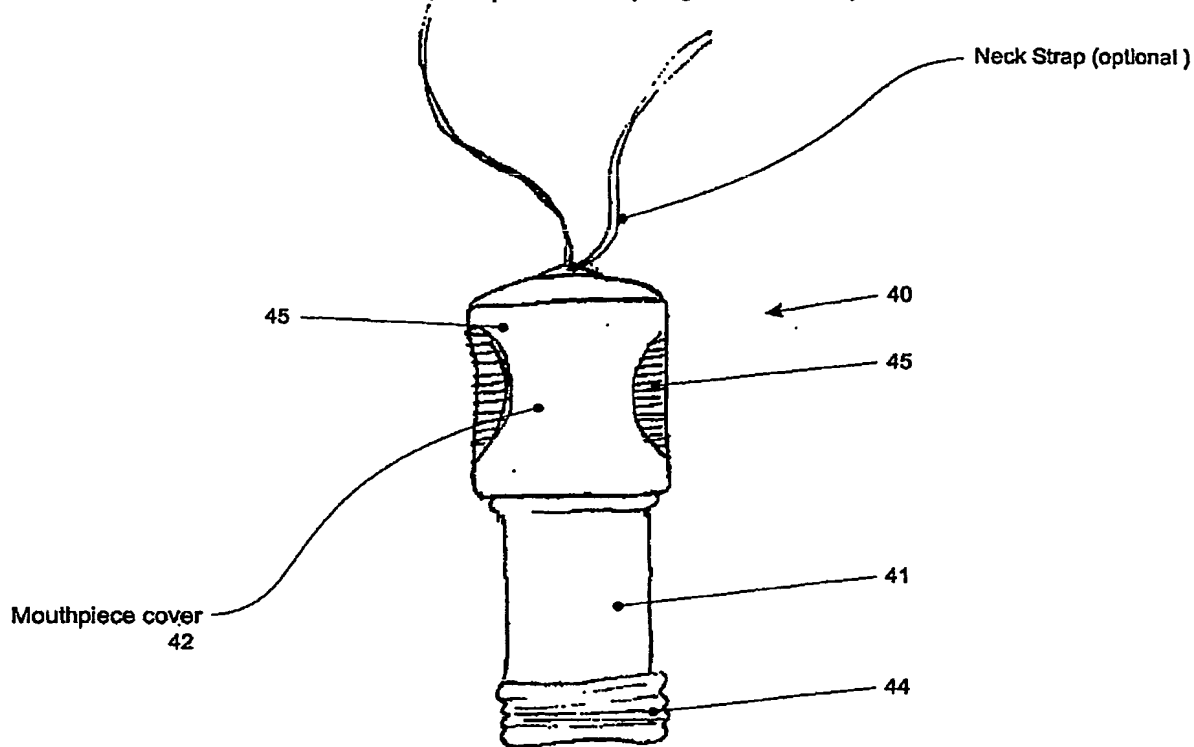


FIGURE 5. (Closed view)

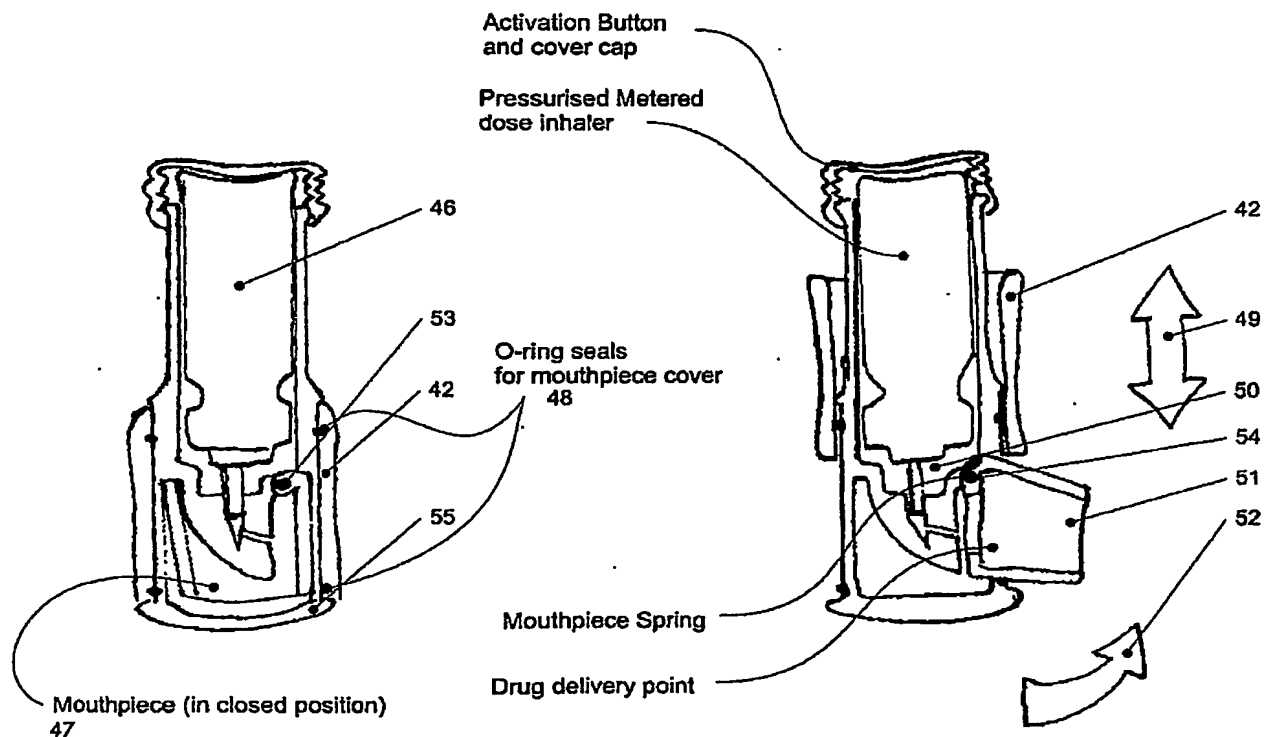


FIGURE 6. (Sectional view)

FIGURE 7.

Medidive Active Sports Unit (Dry Powder Inhaler)

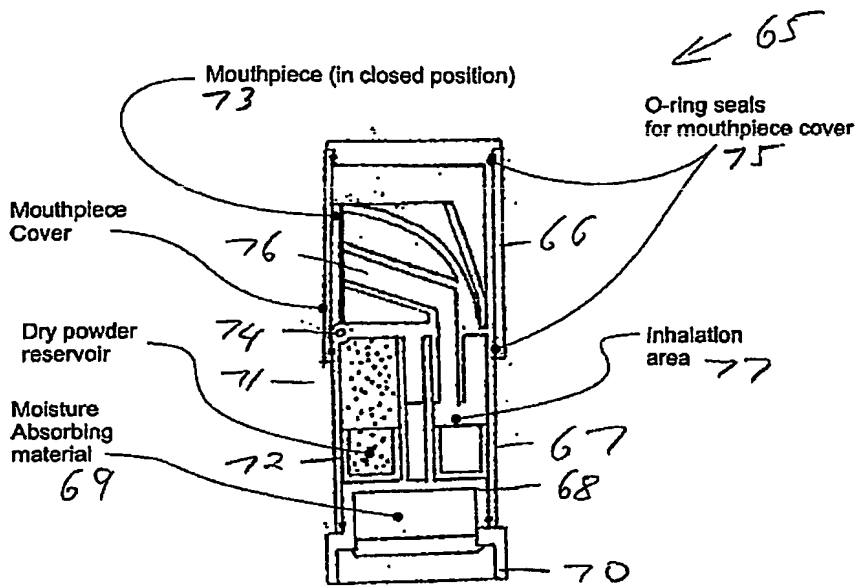


FIGURE 8.

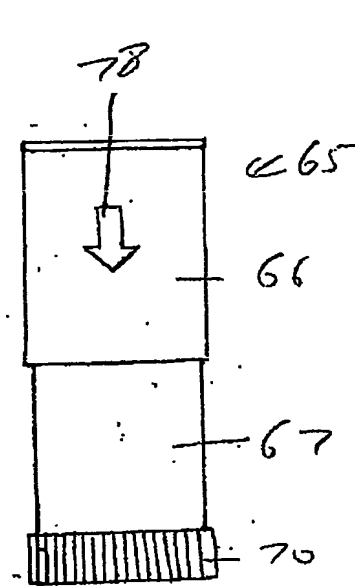


FIGURE 9.

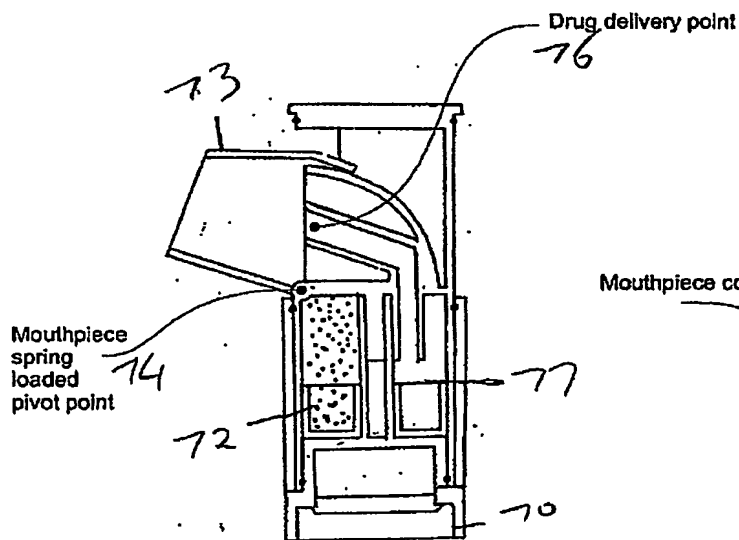


FIGURE 10.

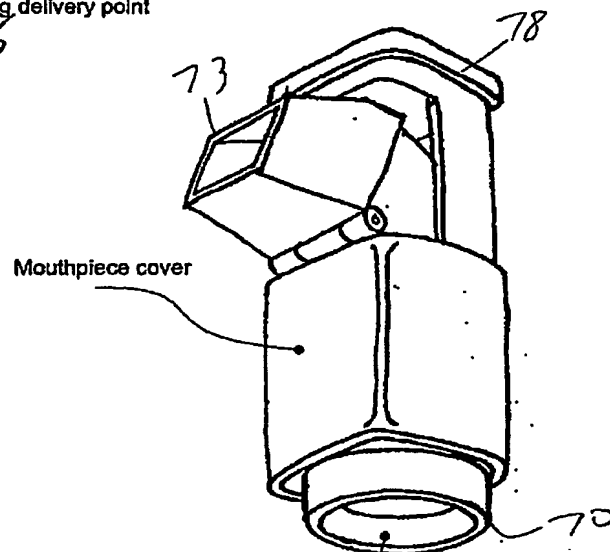
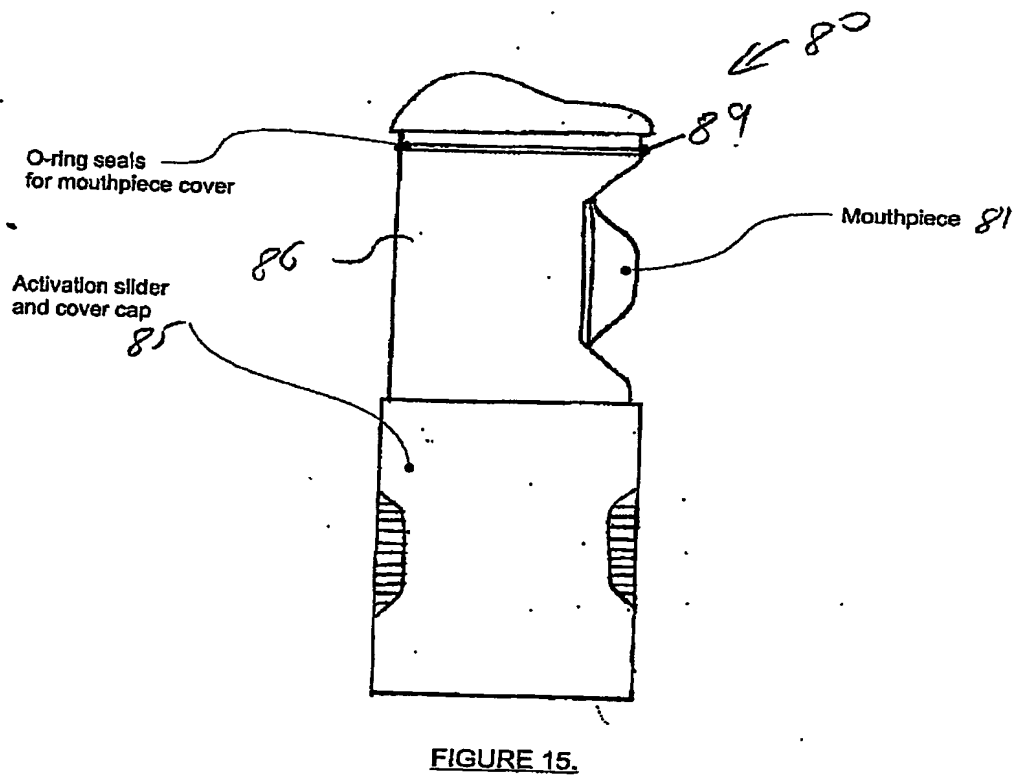
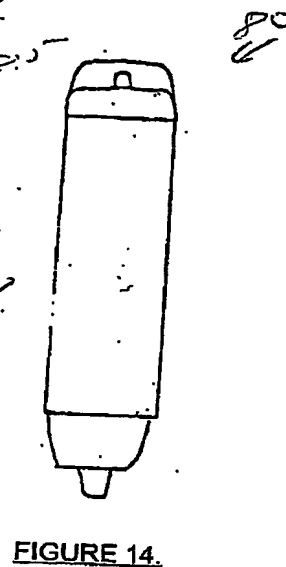
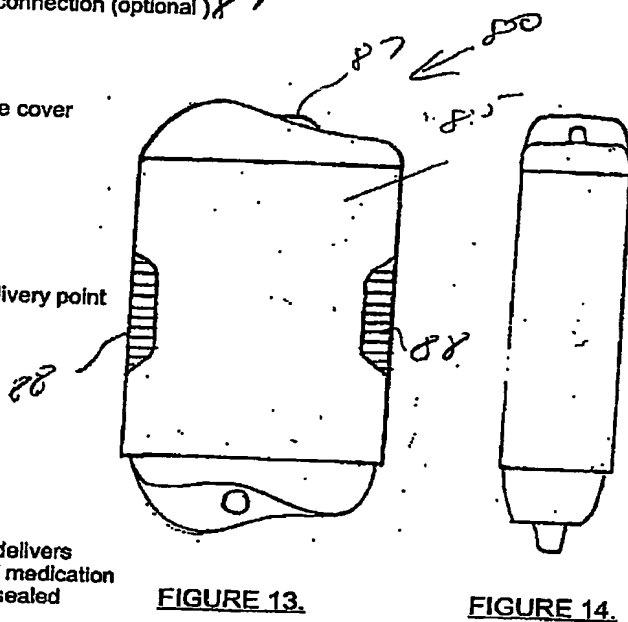
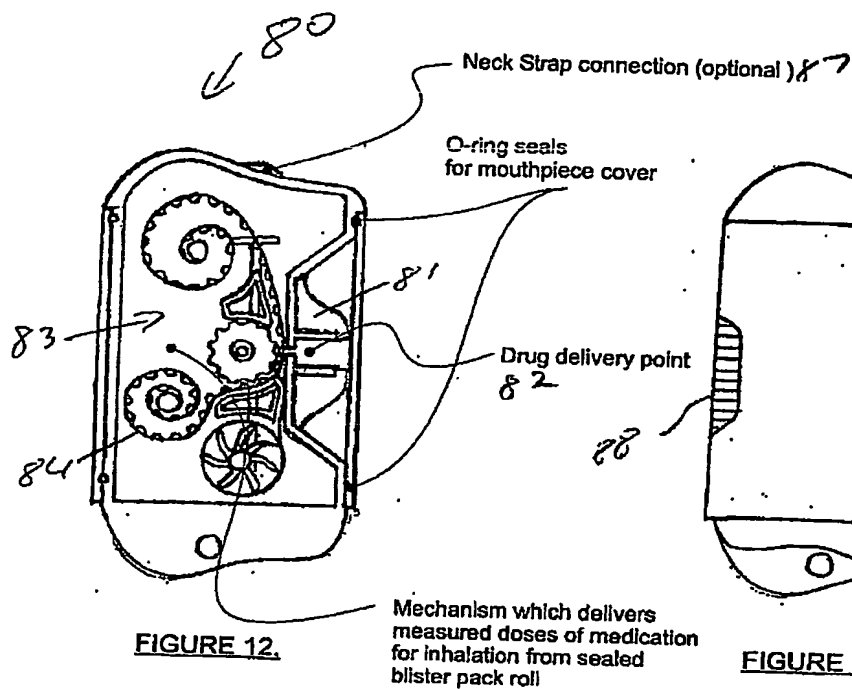


FIGURE 11.

Activation Twist Base
(moves dose of powder
into inhalation area)

Medidive Active Sports Unit (Dry Powder Capsules)



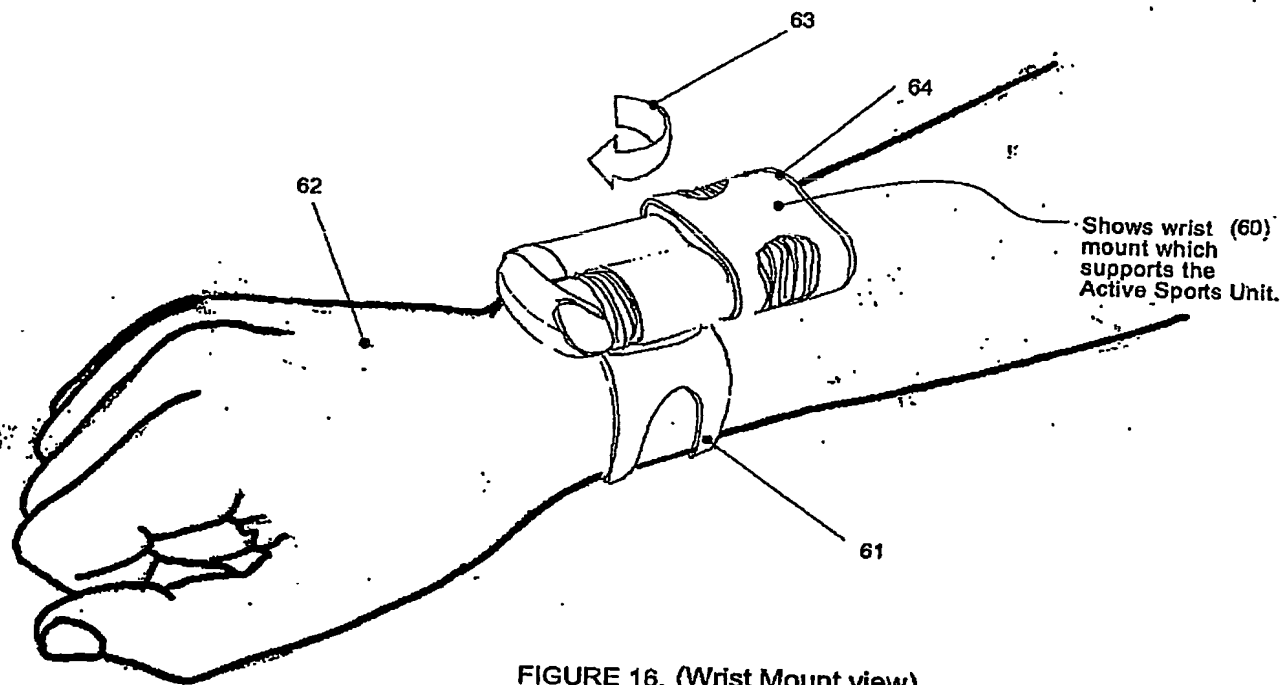


FIGURE 16. (Wrist Mount view)

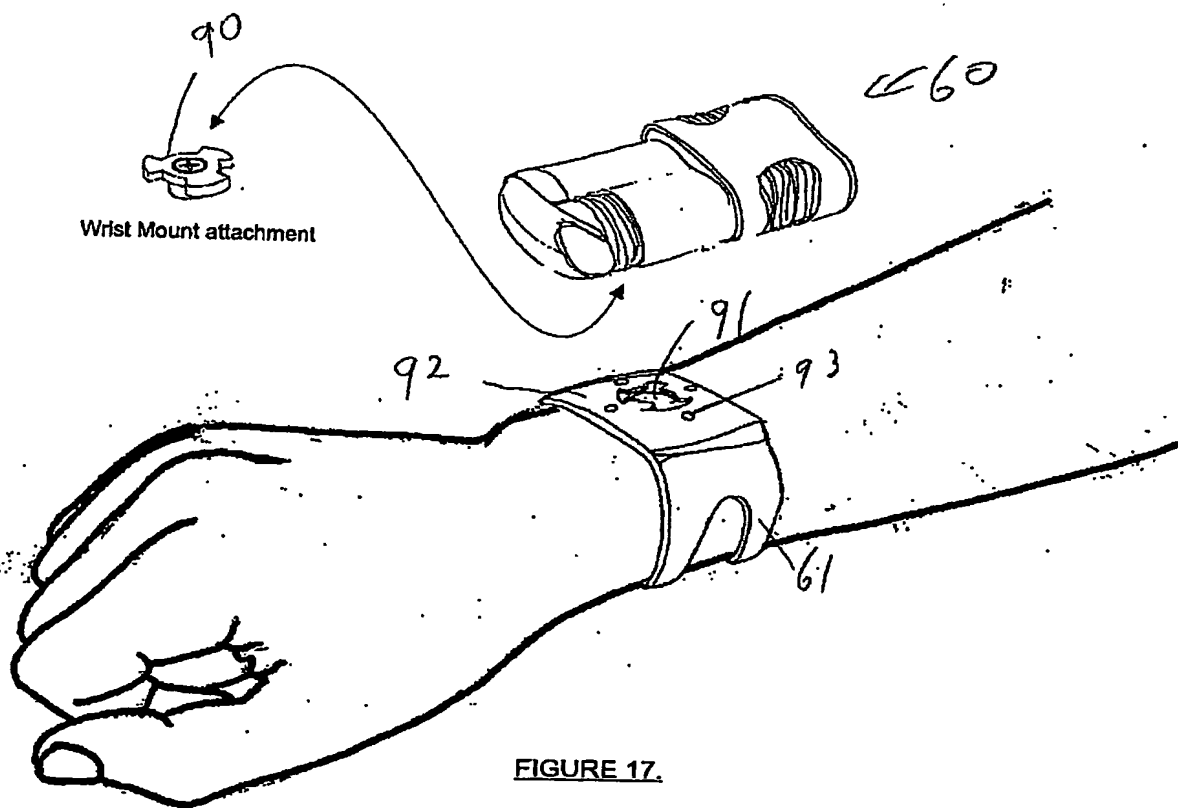


FIGURE 17.

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